

## General

### Guideline Title

Consensus statement on effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytopathology from the College of American Pathologists and Association of Directors of Anatomic and Surgical Pathology.

### Bibliographic Source(s)

Nakhleh RE, Myers JL, Allen TC, DeYoung BR, Fitzgibbons PL, Funkhouser WK, Mody DR, Lynn A, Fatheree LA, Smith AT, Lal A, Silverman JF. Consensus statement on effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytopathology from the College of American Pathologists and Association of Directors of Anatomic and Surgical Pathology. Arch Pathol Lab Med. 2012 Feb;136(2):148-54. [34 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

#### Definitions

*Urgent Diagnosis:* A medical condition that, in most cases, should be addressed as soon as possible. *Significant, Unexpected Diagnosis:* A medical condition that is clinically unusual or unforeseen and should be addressed at some point in the patient's course.

#### Consensus Statements

1. Each institution should create its own policy regarding *Urgent Diagnoses* and *Significant, Unexpected Diagnoses* in Anatomic Pathology. This policy should be separate from critical result or panic value policies in clinical pathology with the expectation of a different time frame for communication.
2. Pathology departments should determine specific urgent diagnoses in collaboration with the clinical staff. These diagnoses should include situations in which urgently conveying the information may directly affect patient care. An example of an urgent diagnosis is an unknown life-threatening infection in an immune-compromised patient. Pathologists, however, should use their experience and judgment to communicate any diagnoses, even if not included in the policy. In hospital practice, approval by the appropriate institutional governing body is recommended.
3. Determination of a significant, unexpected diagnosis is heavily dependent on the pathologist's judgment as a physician. By their nature, significant, unexpected diagnoses cannot always be anticipated. Examples such as a frozen section–permanent section discordance that affects patient care or a clinically unsuspected malignancy may be listed in the policy.
4. Pathologists should communicate urgent diagnoses as soon as possible because it may directly affect patient care, but each institution should

establish a reasonable time frame. The consensus statement authors recommend no longer than the same day on which the diagnosis is made. Communication of significant, unexpected diagnoses should occur as soon as practical; pathologists may exercise their judgment as to the appropriate timing of communication.

5. Pathologists should communicate verbally and directly with physicians, but other satisfactory methods of communication may be established and validated by each institution. Backup communication plans should be developed for those circumstances in which a physician is not available.
6. Pathologists should document the communication. This can be done in the original pathology report, as an addendum, in the electronic medical record, or by another mechanism. Documentation should include the person with whom the case was discussed, the time and date, and when appropriate, the means of communication.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Patients with urgent diagnoses and significant, unexpected diagnoses

Note: *Urgent diagnosis* is defined as a medical condition that, in most cases, should be addressed as soon as possible. *Significant, unexpected diagnosis* is defined as a medical condition that is clinically unusual or unforeseen and should be addressed at some point in the patient's course.

### Guideline Category

Diagnosis

### Clinical Specialty

Pathology

### Intended Users

Health Care Providers

Hospitals

Physicians

### Guideline Objective(s)

To promote effective communication of urgent and significant, unexpected diagnoses in surgical pathology and cytology

### Target Population

Patients with urgent diagnoses and significant, unexpected diagnoses

### Interventions and Practices Considered

1. Creating of institution-specific policy

2. Determination of specific urgent diagnoses by pathology department and clinical staff
3. Communication of urgent diagnoses as soon as possible
4. Verbal and direct communication with physicians with backup plan in place
5. Documentation of communication

## Major Outcomes Considered

- Effectiveness of communication of diagnosis
- Timeliness of communication of diagnosis

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Literature Search

The Work Group conducted a computerized search during May 2010 to February 2011 of the following electronic databases: Ovid MEDLINE (Ovid, New York, New York), CSA Illumina Conference Papers Index (ProQuest, Ann Arbor, Michigan), and Google Scholar (Google, Mountain View, California), for English language only articles from 1990 through February 2011. All study designs and publication types were included. In addition, the Work Group requested the George D. Lundberg 1972 article "When to Panic Over Abnormal Values." The search used the following terms:

- (Anatomic pathology OR surgical pathology OR cytopathology OR radiology OR cardiology) AND
- ([Critical OR significant OR unexpected] AND [values OR diagnosis OR results])

Reference lists from identified articles were scrutinized for articles not identified in the above search. A search of the LexisNexis database (Reed Elsevier Inc., New York, New York) was also conducted to evaluate and understand claims, judgments, and settlements against pathologists in which communication failure was the primary reason.

Studies were selected for full-text review based on the following criteria: (1) the abstract referred to pathology (except autopsy or forensic), cardiology, or radiology; (2) the abstract included or implied one or more of the terms *critical*, *panic values*, *urgent*, *significant*, or *unexpected*; and (3) the abstract addressed communication or reporting.

### Number of Source Documents

Nine studies underwent data extraction to capture evidence in support of the recommendations.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Not Given)

### Rating Scheme for the Strength of the Evidence

Not stated

## Methods Used to Analyze the Evidence

### Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The 128 studies that met the search term requirements underwent an inclusion-exclusion, dual independent review conducted by the chair and a member, with a third member referee for nonconsensus abstracts. Sixty-four articles (50%) made it through full review, and 19 articles (15%) were determined to have the most relevance. Table 1 (in the original guideline document) includes the criteria for evaluation.

The 19 articles determined to have most relevance were analyzed to determine the strength of evidence for the recommendations. Of the 19, 10 (53%) were eliminated: 8 for study design not of interest and 2 for duplicate data. Of the remaining 9 studies, 6 (67%) represented surveys, 2 (22%) were time series, and 1 (11%) was a randomized, controlled study. These 9 studies underwent data extraction to capture evidence in support of the recommendations. Each study was assessed for strength of evidence, which consists of level of evidence, quantity, size of the effect, statistical precision, and quality assessment (risk of bias), of included studies. Also taken into account were the study components of consistency, clinical impact, generalizability, and applicability to anatomic pathology when determining the strength of evidence score for individual studies. The studies' individual component scores derived from predetermined criteria, generated the overall grade for the strength of evidence. The scientific quality of the randomized, controlled trial was assessed using the Scottish Intercollegiate Guideline Network (SIGN) 50 instrument (SIGN, Edinburgh, Scotland), and its quality was poor. The scientific quality of the time series was determined using the Ramsay et al instrument, and the quality of both studies was good. However, both studies lacked comparative control groups.

Based on the data extraction of nine studies and relevance to the recommendations, the overall strength of evidence was poor. For a detailed analysis of the evaluation of the strength of evidence, please refer to the "Supplemental Material" document (see the "Availability of Companion Documents" field).

## Methods Used to Formulate the Recommendations

### Expert Consensus

## Description of Methods Used to Formulate the Recommendations

### Panel Composition and Process

The College of American Pathologists (CAP) Center and Association of Directors of Anatomic and Surgical Pathology (ADASP) convened a work group of experts in anatomic pathology to address what constitutes a critical value in anatomic pathology and how best to ensure proper and timely communication of those results. Both organizations used their respective organization's approval processes in formal review and appointment of the project, chair, and work group (WG) members.

The WG met in September 2010; additional work on the project was completed through teleconference Webinars, collaboration site access (Oracle WebCenter Spaces v11.1.1.2.0, Oracle Corporation, Redwood Shores, California), and electronic mail by all members of the WG. The method used to create the recommendations was expert consensus. Resolution of discordant ideas was obtained by majority consensus of the WG member.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

# Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Feedback of the draft recommendations was solicited from Association of Directors of Anatomic and Surgical Pathology (ADASP) members, College of American Pathologists (CAP) scientific resource committees, CAP members, other pathology societies, and external reviewers via public comment hosted on the CAP Web site (<http://www.cap.org/center> ) from March 11, 2011, through April 10, 2011 (last accessed April 10, 2011). The CAP Center Subcommittee and the ADASP Council provided final review and approval.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

Table 2 in the original consensus statement provides a description of the nine studies that underwent data extraction.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytopathology

### Potential Harms

See "Cautionary Notes" in the original guideline document for situations that may be problematic and not easily addressed by policy.

## Qualifying Statements

### Qualifying Statements

- Practice guidelines and consensus statements reflect the best available evidence and majority expert agreement supported in practice. They are intended to assist physicians and patients in clinical decision making and to identify questions and settings for further research. With the rapid flow of scientific information throughout medicine and especially in pathology and laboratory medicine, new evidence may emerge between the time an updated guideline was submitted for publication and when it is read or appears in print or online. These documents are reviewed periodically as well as after the publication of substantive and high-quality medical evidence that could potentially alter the original guideline recommendations.
- This manuscript and its recommendations are meant only to address the topics within the scope of the guideline or consensus statement. They are not applicable to interventions, diseases, or stages of diseases not specifically identified.
- Guidelines and consensus statements cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the treating physician or other health care provider, relying on independent experience and knowledge of the patient, to determine the best course of treatment for the patient. Accordingly, adherence to any guideline or consensus statement is voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances and preferences.
- The College of American Pathologists (CAP)/Association of Directors of Anatomic and Surgical Pathology (ADASP) guidelines and consensus statements describe the use of communications of findings, procedures, and therapies in clinical practice and cannot be assumed

to apply to the use of interventions in the context of other settings. The CAP and ADASP assume no responsibility for any injury or damage to persons or property arising out of or related to any use of the CAP/ADASP guidelines or consensus statements or for any errors or omissions.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

Staying Healthy

### IOM Domain

Effectiveness

Timeliness

## Identifying Information and Availability

### Bibliographic Source(s)

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### Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2012 Feb

## Guideline Developer(s)

Association of Directors of Anatomic and Surgical Pathology - Professional Association

College of American Pathologists - Medical Specialty Society

## Source(s) of Funding

College of American Pathologists

Association of Directors of Anatomic and Surgical Pathology

## Guideline Committee

College of American Pathologists (CAP)/Association of Directors of Anatomic and Surgical Pathology (ADASP) Work Group

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

All members of the Work Group (WG) complied with the College of American Pathologists (CAP) conflicts of interest policy dated April 2010, which requires disclosure of financial or other interests that may have an actual, potential, or apparent conflict (see Supplemental Material document [see the "Availability of Companion Documents" field] for details). All WG members were required to disclose any new conflicts continuously, and no conflicts were disclosed throughout the project.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [College of American Pathologists Web site](#) .

Print copies: Available from the College of American Pathologists, 305 Waukegan Road, Northfield, IL 60093-2750.

## Availability of Companion Documents

The following are available:

- The College of American Pathologists (CAP) and Association of Directors of Anatomic and Surgical Pathology (ADASP): effective communication of urgent and significant unexpected diagnoses in surgical pathology and cytopathology. Supplemental material. Electronic copies: Available in Portable Document Format (PDF) from the [College of American Pathologists \(CAP\) Web site](#) .
- Summary of consensus statement on effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytopathology. Summary. 2012 Feb. 1 p. electronic copies: Available in PDF from the [CAP Web site](#) .

The appendix of the [original guideline document](#)  contains information on the legal and regulatory standards as of July 2011.

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on March 6, 2013. The information was verified by the guideline developer on March 15, 2013.

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